



Atty. Dkt. No. 028622-0102

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Bernd DORKEN et al.

Title: NOVEL CD19xCD3 SPECIFIC POLYPEPTIDES AND USES THEREOF

Appl. No.: 09/673,735

Filing Date: 12/27/2000

Examiner: Larry Ronald Helms

Art Unit: 1642

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

03/29/2005 MGE BREM1 00000053 09673735  
180.00 DP  
03 FC:1806

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

**FEE**

A fee in connection with submission of a supplemental information disclosure statement under 37 CFR §1.97(c) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.

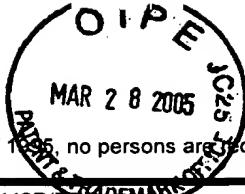
The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 28, 2005

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5483  
Facsimile: (202) 672-5399

By Richard C. Peet (40,153)  
for Richard C. Peet  
Attorney for Applicant  
Registration No. 35,792



MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/P-1449B  
**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Date Submitted: March 28, 2005

(use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

<b>Application Number</b>	09/673,735
<b>Filing Date</b>	12/27/2000
<b>First Named Inventor</b>	Bernd DORKEN
Group Art Unit	1642
Examiner Name	Larry Ronald Helms

Sheet

1 of 2

**Attorney Docket Number**

028622-0102

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

## FOREIGN PATENT DOCUMENTS

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>8</sup>
	D1	ANDERSON, P. M., et al., "G19.4(αCD3) x B43(αCD19) Monoclonal Antibody Heteroconjugate Triggers CD19 Antigen-Specific Lysis of t(4;11) Acute Lymphoblastic Leukemia Cells by Activated CD3 Antigen-Positive Cytotoxic T Cells, <i>Blood</i> , vol. 80, no. 11, pp. 2826-2834 (1992).	
	D2	BOHLEN, H., et al., "Cytolysis of Leukemic B-Cells by T-Cells Activated via Two Bispecific Antibodies", <i>Cancer Research</i> , vol. 53, pp. 4310-4314 (1993).	
	D3	HAAGEN, I., et al., "Killing of Autologous B-Lineage Malignancy Using CD3 x CD19 Bispecific Monoclonal Antibody in End Stage Leukemia and Lymphoma", <i>Blood</i> , vol. 84, no. pp. 556-563 (1994).	
	D4	HAAGEN, I., et al., "Unprimed CD4+ and CD8+ T cells can be rapidly activated by a CD3 x CD19 bispecific antibody to proliferate and become cytotoxic", <i>Cancer Immunol. Immunother.</i> , vol. 39, pp. 391-396 (1994).	
	D5	DE GAST, G. C., et al., "Clinical Experience with CD3 x CD 19 Bispecific Antibodies in Patients with B Cell Malignancies", <i>J. Hema.</i> , vol. 4, pp. 433-437 (1995).	

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO)

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

MAR 28 2005

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Date Submitted: March 28, 2005

(use as many sheets as necessary)

Sheet

2

of

2

## Complete if Known

Application Number	09/673,735
Filing Date	12/27/2000
First Named Inventor	Bernd DORKEN
Group Art Unit	1642
Examiner Name	Larry Ronald Helms

Attorney Docket Number 028622-0102

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	D6	WEINER, G. J., et al., "Bispecific Monoclonal Antibody Therapy of B-Cell Malignancy", Leukemia and Lymphoma, vol. 16, pp. 199-207 (1995).	
	D7	HAAGEN, I., "Performance of CD3 x CD19 Bispecific Monoclonal Antibodies in B Cell Malignancy", Leukemia and Lymphoma, vol. 19, pp. 381-393 (1995)	
	D8	HAAGEN, I., et al., "The Efficacy of CD3 x CD19 Bispecific Monoclonal Antibody (BsAb) in a Clonogenic Assay: The Effect of Repeated Addition of BsAb and Interleukin-2", Blood, vol. 85, no. 11, pp. 3208-3212 (1995).	
	D9	MACK, M., et al., "A small bispecific antibody construct expressed as a functional single-chain molecule with high tumor cell cytotoxicity", Pro. Natl. Acad. Sci., vol. 92, pp. 7021-7025 (1995).	
	D10	KIPRIYANOV, S. M., et al., "Bispecific diabody for lysis of human B-lineage leukemia cells", The Fourteenth International Conf. on Adv. In the Application of Monoclonal Antibodies in Clinical Oncology", p. 29 Thira Santorini, Greece (May 5-7, 1997).	
	D11	DE JONGE J., et al., "Bispecific antibody treatment of murine B cell lymphoma", Cancer Immunol. Immunother., vol. 45, pp. 162-165 (1997).	
	D12	KUFER, P., et al., "Construction and biological activity of a recombinant bispecific single-chain antibody designed for therapy of minimal residual colorectal cancer", Cancer Immunol. Immunother., vol. 45, pp. 193-197 (1997).	
	D13	KIPRIYANOV, S. M., et al., "Bispecific CD3 x CD 19 Diabody for T Cell-Mediated Lysis of Malignant Human B Cells", Int. J. Cancer, vol. 77, pp. 763-772 (1998).	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.